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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,691,336 was filed on March 21, 2008, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, EMEND® for injection (fosaprepitant), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved.¹ Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

¹The filing of the application on March 21, 2008, was timely, given the NDA approval date of January 25, 2008. Applicant, however, misidentified at paragraph (5) on page 5 of the application the last day the application may be submitted as March 25, 2008, pursuant to 37 C.F.R. § 1.740(a)(5). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA grants permission for commercial marketing or use. The absolute deadline for filing the present PTE Application was thus March 24, 2008, or sixty days from January 25, 2008, starting the count of the sixty-day period on January 25, 2008.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

A handwritten signature in cursive script, appearing to read "Mary C. Till", is written over a horizontal line.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner

for Patent Examination Policy

cc: J. Eric Thies
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